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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,216	05/31/2001	Robert D. Ainsworth	3764.P003	2384
8791 7590 02/01/2008 BLAKELY SOKOLOFF TAYLOR & ZAFMAN 1279 OAKMEAD PARKWAY SUNNYVALE, CA 94085-4040			EXAMINER ROZANSKI, MICHAEL T	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 02/01/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/872,216	AINSWORTH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Rozanski	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/07 has been entered.

### ***Claim Objections***

Claims 17 and 20 are objected to because of the following informalities:

Claim 17 depends from claim 16, which has been cancelled.

Claim 20 appears to be a product by process. It appears Applicant intended to claim that the distal tip is formed from a metal.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 8, 9, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Specifically, these claims are not further limiting in view of the amendments with respect to the independent claim from which they depend.

Claims 3, 4, 10, 17, 22, and 23 are rejected under 35 U.S.C. 112, second paragraph. It is unclear how an optical fiber can be "configured to sense vessel and blood characteristics" because there is no claimed element that processes the measured optical data. For example, some type of data processing system would be necessary to analyze/determine this information.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 18, and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tenerz et al** (US 4,941,473 –previously cited) in view of **Einzig** (US 5,178,153) and **Goldenberg** (US 4,830,460).

Tenerz et al. discloses a therapeutic guidewire having an optical fiber (3) extending along the length of the guidewire for measuring intravascular pressure (see Figure 2). Tenerz et al. furthermore teaches a high strength proximal core section by

teaching use of tightly wound wire at the proximal section and flexible distal core by teaching use of flexible, resilient wire at the distal section (see col. 2, lines 25-33).

In regards to claim 4, the teaching to intravascular pressure measurement of Tenerz et al. is an example of hemodynamic blood characteristics. In regards to claim 5 the references clearly recites that the guidewire is for guiding a catheter (see Abstract). Therefore although the catheter structure is not positively recited in the reference, it is inherent that the guidewire is operatively coupled to a catheter. The sole purpose of having a guidewire is to guide a probe (i.e. catheter) coupled to it. The operative coupling of a catheter to a guidewire is inherent. In regards to claim 18, Tenerz et al teach that the components of the guidewire can contain a compound making it visible under radiography or having a radiopaque substance as claimed by applicant (column 3 lines 23-27).

Tenerz et al. do not expressly teach of an optical fiber that both senses and transmits diagnostic information. In the same field of endeavor, Einzig (US 5,178,153) is directed to an optical fiber pressure sensing fluid flow device for in vivo determination of blood flow in arteries (col. 6, lines 45-67). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify Tenerz et al, to use an optical fiber that senses pressure as taught by Einzig instead of using a pressure sensor, because sensing pressure directly allows for faster measurement.

Tenerz et al. also does not expressly teach said optical fiber being slideable relative to the guidewire or being exposed to a vessel through the distal tip. In the same field of endeavor, Goldenberg teaches that the optical fiber is advanced (i.e. slideable)

along a guidewire until the fiber is positioned adjacent a desired region in a blood vessel (col 3, lines 37-55). The fiber is advanced until it is exposed to a vessel through a distal tip (see figure 11) which may be covered with a transparent balloon (col 10, lines 62-64). Furthermore, optical fiber 14 is used to sense blood characteristics as an image and transmits it to a video camera 16 for data processing by means of a video coupler 18 for viewing on monitor 20 (see figure 1). It would have been obvious to the skilled artisan to modify Tenerz/Einzig, to have a slideable optical fiber that is exposed to a vessel through the distal tip as taught by Goldenberg, in order to allow the optical fiber to be removed and reinserted under necessary conditions.

Claims 11-15, 17, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tenerz et al, Einzig, and Goldenberg** as applied to claim 6 further in view of **Jafari** (previously cited).

Goldberg teaches of an atraumatic distal tip covered by polymeric balloon (see figure 11) and flexible jacket that may be made of a UV cured acrylate compound that forms polymeric plastics (col 6, lines 27-46). However, Tenerz et al/Eingiz/Goldenberg do not teach specific structure components of guidewire comprising distal core section, proximal core section, connecting member, flexible coil disposed about distal core section, shaped ribbon coupled to distal core section, clear polymeric jacket disposed about distal core section, said clear polymeric jacket coupled to at least one point along an outer surface of the distal core section, and the atraumatic distal tip coupled to a distal end of clear polymeric jacket.

Figure 1 of Jafari discloses a therapeutic guidewire (10) comprising an elongated body having a distal core section (12) coupled to a proximal core section (11) by a connecting member (13) and an atraumatic distal tip (24) formed at a distal end (21) of the distal core section (12). The device further comprises a flexible coil (22) disposed about the distal core section (12) and coupled to at least one point (25) along the distal core section (12). A shaped ribbon (23) is shown within the therapeutic guidewire (10), columns 5-6. The atraumatic distal tip (24) is coupled to the distal end of the flexible coil (22). The atraumatic tip is formed with a solder (includes combination of gold and tin which satisfies applicant's limitation to metal or hardenable polymeric material (col 5, lines 56-61)).

The Jafari reference provides evidence that said improved guidewire structure enables advanced access throughout and is easily maneuverable within the vastly branched vascular (col 8 lines 1-29).

It would have been obvious to a person of ordinary skill in the art to incorporate the guidewire structure limitations of Jafari into the system of Tenerz et al/Einzig/Goldenberg because the structure of Jafari improves on the movement of a guidewire within the vascular of the body.

### ***Response to Arguments***

Applicant's arguments with respect to claim 1-15 and 17-32 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MR



ERIC F. WINAKUR  
PRIMARY EXAMINER